UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

B.F., a minor, BETH FORBES, individually and as next friend of B.F., and THOMAS FORBES, individually and as next friend of B.F.,	)	No. 4:12-CV-1760 CAS
Plaintiffs,	)	
v.	)	
ABBOTT LABORATORIES, INC., et al.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on defendant Abbott Laboratories, Inc.'s ("Abbott") motion for summary judgment. Plaintiffs oppose the motion. The motion is fully briefed and ready for decision. For the following reasons, the motion will be denied.

Background

In this products liability action, plaintiffs Thomas and Beth Forbes and their minor son B.F. ("plaintiffs") assert claims against Abbott arising out of injuries resulting from B.F.'s exposure *in utero* to the medicine Depakote. Beth Forbes began taking Depakote two years before B.F.'s birth to treat her bipolar disorder. Plaintiffs allege B.F. sustained serious and permanent injures and damages as a result of his mother's ingestion of Depakote during pregnancy, specifically that B.F. was diagnosed with spina bifida.

Plaintiffs brought this action against Abbott in seven counts, only two of which remain: Strict Liability—Failure to Warn (Count I) and Negligence—Failure to Warn (Count III). Abbott moves for summary judgment on these remaining counts, asserting that (1) Depakote's

warnings were adequate as a matter of law; and (2) plaintiffs cannot establish that the alleged inadequate warnings were the proximate cause of plaintiffs' injuries.

Summary Judgment Standard

The standards applicable to summary judgment motions are well settled. Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

The initial burden is placed on the moving party. City of Mt. Pleasant, Iowa v. Associated Elec. Co-op., Inc., 838 F.2d 268, 273 (8th Cir. 1988) (the moving party has the burden of clearly establishing the non-existence of any genuine issue of fact that is material to a judgment in its favor). Once this burden is discharged, if the record does in fact bear out that no genuine dispute exists, the burden then shifts to the non-moving party who must set forth affirmative evidence and specific facts showing there is a genuine dispute on that issue. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

In passing on a motion for summary judgment, this Court is required to view the facts in a light most favorable to the non-moving party and the Court must give the non-moving party the benefit of any inferences that can logically be drawn from those facts. Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Buller v. Buechler, 706 F.2d 844, 846 (8th Cir. 1983). Moreover, this Court is required to resolve all conflicts in favor of the non-moving party. Robert Johnson Grain Co. v. Chemical Interchange Co., 541 F.2d 207, 210 (8th Cir. 1976).

Facts

Beginning in 1999, Beth Forbes began suffering from mental illness, for which she received medical treatment. During a June 2002 hospitalization, she was diagnosed as suffering from bipolar disorder/manic depression.

In or around April 2003, Beth Forbes came under the care of Dr. Raziya Mallya ("Dr. Mallya"), a psychiatrist, who began treating Mrs. Forbes for her bipolar disorder. Starting in April 2003, Dr. Mallya prescribed Depakote Extended Release ("Depakote") tablets, as well as Geodon and Wellbutrin, for treatment of Mrs. Forbes' bipolar disorder. Dr. Mallya prescribed Depakote as a mood stabilizer.

In January 2005, Mrs. Forbes became pregnant with B.F. She testified that she had been taking Depakote at that time for treatment of her bipolar disorder. Mrs. Forbes stopped taking Depakote after she found out that she was pregnant with B.F.

In September 2005, Beth Forbes gave birth to B.F. B.F. has been diagnosed with spina bifida as well as some other conditions that plaintiffs claim are secondary to spina bifida, namely: hydrocephalus, Chiari type II malformation, club feet deformity, bilateral hip dislocations, tethering of spinal cord (now untethered), sensorineural hearing loss in right ear, and neurogenic bowel and bladder leading to incontinence of feces and urine. Plaintiffs claim all of B.F.'s physical limitations stem from and are attributable to B.F.'s spina bifida.

At all relevant times when Mrs. Forbes was taking Depakote from 2003 to 2005, Depakote's label included specific warnings regarding the risk of spina bifida due to *in utero* exposure. The Depakote prescribing information (often referred to as "the label") included a Block Box warning in all caps that warned of the risks of neural tube defects. The black box provided:

> **TERATOGENICITY:**
> VALPROATE [DEPAKOTE] CAN PRODUCE TERATOGENIC EFFECTS SUCH AS NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA), ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS. THIS IS ESPECIALLY IMPORTANT WHEN THE TREATMENT OF A SPONTANEOUSLY REVERSIBLE CONDITION NOT ORDINARILY ASSOCIATED WITH PERMANENT INJURY OR RISK OF DEATH (E.G., MIGRAINE) IS CONTEMPLATED. SEE WARNINGS, INFORMATION FOR PATIENTS.
> AN INFORMATION SHEET DESCRIBING THE TERATOGENIC POTENTIAL OF VALPROATE IS AVAILABLE FOR PATIENTS.

(Abbott SOF ¶ 15.)

A ten-paragraph warning in the "Usage in Pregnancy" subsection of the 2003 and 2004 Depakote labels provided in relevant part:

> ACCORDING TO PUBLISHED AND UNPUBLISHED REPORTS, VALPROIC ACID MAY PRODUCE TERATOGENIC EFFECTS IN THE OFFSPRING OF HUMAN FEMALES RECEIVING THE DRUG DURING PREGNANCY. THE DATA DESCRIBED BELOW WERE GAINED ALMOST EXCLUSIVELY FROM WOMEN WHO RECEIVED VALPROATE TO TREAT EPILEPSY. THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTIEPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITAL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION WITH THE USE OF OTHER ANTIEPILEPTIC DRUGS.
> THE INCIDENCE OF NERUAL TUBE DEFECTS IN THE FETUS MAY BE INCREASED IN MOTHERS RECEIVING VALPROATE DURING THE FIRST TRIMJESTER OF PREGNANCY. THE CENTERS FOR DISEASE CONTROL (CDC) HAS ESTIMATED THE RISK OF VALPROIC ACID EXPOSED WOMEN HAVING CHILDREN WITH SPINA BIFIDA TO BE APPROXIMATELY 1 TO 2%.
> OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE.

* * * * *

> The prescribing physician will wish to weigh the benefits of therapy against the risks in treating or counseling women of childbearing potential. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

* * * * *

> Tests to detect neural tube and other defects using current accepted procedures should be considered a part of routine prenatal care in childbearing women receiving valproate.

(Abbott SOF ¶¶ 16-17.)

Discussion

(A) Failure to Warn

Abbott moves for summary judgment on the adequacy of its warning because the Depakote label expressly warned of the risks of spina bifida, the injury experienced by B.F., and thus Abbott asserts its warning was adequate as a matter of law. Plaintiffs respond that there remains a genuine dispute regarding the adequacy of Abbot's warning, as demonstrated by expert evidence that Abbott's warning was informationally deficient, inaccurate, and misleading.

Under Missouri law, the elements of a cause of action for strict liability for failure to warn are: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning to the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning. See Moore v. Ford Motor Co., 332 S.W.3d 749, 756 (Mo. 2011). "In applying these elements, Missouri law recognizes that a product may be rendered unreasonably dangerous and therefore actionable

because of the absence of a warning concerning use or misuse, or because the warning that has been given is informationally deficient." Id. (internal quotations omitted) (citing Nesselrode v. Exec. Beechcraft, Inc., 707 S.W.2d 371, 382 (Mo. banc 1986)).

Abbott states that its label featured a clear and prominent warning regarding the precise risk at issue in this case—the risk of spina bifida—and clearly alerted physicians of the risk of birth defects. Further, based on Dr. Mallya's testimony, she was aware of Depakote's teratogenicity and the risk of spina bifida at the time she prescribed Depakote to Ms. Forbes. Abbott asserts that the adequacy of Depakote's warning cannot be a jury question in this case because Dr. Mallya was aware of the risk of spina bifida when she prescribed Depakote to Mrs. Forbes, and Dr. Mallya agreed that the Depakote warning label warned of the risk of spina bifida.

Plaintiffs have produced the expert opinions of Cheryl D. Blume, Ph.D., to establish that Abbott's label was inadequate for the following reasons, among others:

(1) Abbott's labeling should have included a statement that Depakote should only be used as a "last line" treatment (i.e., only if other treatment options have failed) in women of childbearing potential;

(2) Abbott should have included the background rate for the incidence of spina bifida to allow for a proper risk-benefit analysis by doctors and their female patients;

(3) Abbott failed to correct the misleading assertion that the relationship between congenital malformations and Depakote was only possible;

(4) Abbott improperly diluted the congenital malformation risk by stating that the rate of spina bifida was 1 percent to 2 percent and that the incidence of other congenital anomalies was unknown. This did not provide all of the information that Abbott knew or should have known about the risk of spina bifida because studies had reported spina bifida/neural tube defect rates as high as 3.8 percent following Depakote monotherapy during pregnancy;

(5) Abbott failed to provide current, complete and accurate information in the labeling and failed to correct obsolete data and information; and

(6) Abbott's labeling failed to advise on the importance of contraceptive use.

While Abbott is correct that Dr. Mallya testified that she knew of the risk of spina bifida, and advised Mrs. Forbes of the risk, this does not necessarily render the Depakote warning label adequate as a matter of law. There is a still a question of fact whether the warning was informationally deficient. In particular, it is questionable whether warning the patient of 1 to 2 percent chance of having a baby with spina bifida if taking Depakote fulfills Abbott's duty under Missouri law to properly warn the doctor of the dangers involved. Under Missouri law, "it is incumbent upon the manufacturer to bring the warning home to the doctor." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (quoting Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967)). Dr. Mallya testified that additional warnings such as "Depakote should only be used to treat pregnant women with epilepsy or bipolar disorder if other medications have failed to control their symptoms," "Depakote should not be administered to a woman of child-bearing potential unless the drug is essential to the management of her condition," or a warning that women should use contraception while using Depakote would have made a difference in her attitude toward Depakote and would have changed her approach to prescribing Depakote. (Mallya Dep. at 81-83.)

Resolving all conflicts in favor of plaintiffs, the Court finds there are genuine issues of material fact which preclude the entry of summary judgment on this claim, including but not limited to whether Abbott should have included on its warning that Depakote should only be used as a last line treatment in women of childbearing potential, the background rate of the incidence of spina bifida in the general population, whether Abbott improperly diluted the

congenital malformation risk, and whether Abbot's warning failed to advise on the importance of contraceptive use. As a result, Abbott's motion for summary judgment as to liability for failure to warn will be denied.

(B) Proximate Cause

To prevail on their failure to warn claims, plaintiffs must establish proximate cause. "To do this, they have to show that the warnings would have altered the behavior of the individuals involved . . . ." Johnson v. Medtronic, Inc., 365 S.W.3d 226, 232 (Mo. Ct. App. 2012) (internal quotation omitted). Missouri law supplies the presumption that a warning, if provided, will be read and heeded. Id.

Abbott claims that the record establishes that Mrs. Forbes' prescribing physician, Dr. Mallya, was fully aware of the risk of spina bifida associated with Depakote when she prescribed the medication. Abbott argues that due to Dr. Mallya's awareness of the risk, no alleged failure to warn by Abbott could have been the proximate cause of B.F's injury. Abbott argues that plaintiffs cannot establish that an adequate warning would have altered Dr. Mallya's decision to prescribe Depakote, and plaintiffs submit no evidence that Abbott's alleged failure to warn caused plaintiffs' injuries.

Contrary to Abbott's assertion, plaintiffs offered evidence to support their position that had Abbott included additional information regarding the teratogenic effects of Depakote on its warning, Dr. Mallya might not have prescribed this medication to Mrs. Forbes. At deposition, Dr. Mallya stated that if Abbott would have included on its warning, "[Depakote] should not be administered to a woman of child-bearing potential unless the drug is essential to the management of her condition," this would have definitely changed her approach to prescribing the medication. (Mallya Dep. at 82.) Dr. Mallya also testified that if the label would have

included a warning that women should use effective contraception while using Depakote, this would also have affected her prescription approach. (Id. at 83.)

Neither party asked Dr. Mallya specifically with respect to Mrs. Forbes whether these additional warnings would have changed her decision to prescribe Mrs. Forbes Depakote. Nor did either party ask whether the additional warnings would have caused Dr. Mallya to recommend Mrs. Forbes use contraception to avoid pregnancy. On summary judgment, however, the Court must view the facts in the light most favorable to plaintiffs and give them the benefit of any logical inference. It is logical to infer from Dr. Mallya's testimony that the additional warnings suggested by plaintiffs' expert would have changed Dr. Mallya's approach to prescribing Depakote to Mrs. Forbes. The Court concludes there are genuine issues of material fact which preclude the entry of summary judgment on this claim. Abbott's motion for summary judgment on the issue of proximate cause will therefore be denied.

Conclusion

For the foregoing reasons, Abbott's motion for summary judgment will be denied.

Accordingly,

IT IS HEREBY ORDERED that defendant Abbott Laboratories, Inc.'s motion for summary judgment is **DENIED**. [Doc. 61]

CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 31st day of March, 2016.